K081654
p 1/3

OCT 10 2008

Non-Confidential Summary of Safety and Effectiveness

6-Oct-08

Omron Healthcare, Inc.
1200 Lakeside Dr.
Bannockburn, IL 60015

Tel – 847-247-5609
Fax – 847-680-6269

Official Contact: Ranndy Kellogg – VP Marketing & Product Development

Proprietary or Trade Name: HEM-9000AI

Common/Usual Name: System, Measurement, Blood-Pressure, Non-invasive

Classification Name/Code: DXN – System, Measurement, Blood-pressure, Non-invasive

Device: Model – HEM-9000AI-X

Predicate Devices: Omron – HEM-9000AI – K050233
AtCor SphygmoCor Px – K012487
AtCor Medical – SphygmoCor CvMS– K070795

Device Description:
The modified HEM-9000AI-X is an oscillometric NIBP measurement device and tonometer Augmentation Index detection device. The HEM-9000AI utilizes both an oscillometric blood pressure detection technology via a cuff wrap at the upper arm as well as a tonometer measurement technology using the radial artery at wrist. The HEM-9000AI-X detects Korotkov (K) sounds for NIBP measurement via oscillometric signal detection and processes the data through its CPU and algorithm within the device. It provides measurements of systolic, diastolic and pulse pressures, as well as pulse rate for adult patients with an upper arm circumference in the range of 7 - 20 inches (17 – 50 cm). AI information is collected via tonometry by the placement of a set of sensors over the radial artery at the wrist. The tonometer applies pressure and compresses the radial artery until sensors detect the pulse wave (PW). The signal is sent back to the central processor which separates the superimposed waveform into the ejected wave and the reflected wave components. The device is self-contained, single unit with both oscillometric and tonometer signal detection built in.

The modification is the addition of a new measured (calculated) parameter referred to as central systolic blood pressure (cSBP) or central blood pressure (cSBP). This new reported measurement is calculated with the late systolic pressure of reflected waves recorded by the applanation tonometry applied to the radial artery.

Indications for Use:

The HEM-9000AI-X is intended to measure systolic and diastolic blood pressure and pulse rate in adults with an arm circumference of 17 - 50 cm (7 - 20 inches), and to calculate a radial augmentation index (AI) and central (aortic) blood pressure which is used on adult patients only.

K081654
p2/3

Non-Confidential Summary of Safety and Effectiveness

6-Oct-08

The HEM-9000AI-X is intended for use in physicians' offices, hospitals, clinics and other medical facilities where non-invasive blood pressure and radial AI measurements/calculations are performed on patients and invasive measurement is contraindicated.

The Augmentation Index (AI) function of the HEM-9000AI-X has not been evaluated on patients who have intra-ventricular conduction delays (VCD).

Patient Population: Adults

Environment of Use: Physicians' offices, hospitals, clinics and other medical facilities

Contraindications: Patients with: known arrhythmia; insufficient peripheral circulation, acute cases of low blood pressure or low temperature; who use a pacemaker; experiencing seizure; should not have blood pressure measurements taken from their arm; with an artificial heart; and whose artery cannot be found by palpation.

Summary of substantial equivalence

Table 1 presents the similarities and differences of the proposed HEM-9000AI-X and the predicate HEM-9000AI, K050233.

Model Name: / **Specification**	**New device HEM-9000AI-X**	**Predicate – K050233 HEM-9000AI**
BP Measurement method	Cuff oscillometric method	Cuff oscillometric method
Augmentation Index (AI) Calculated parameter	Applanation tonometry cSBP	Applanation tonometry Not available
Measurement range	Pressure: 0 to 299 mmHg Pulse Rate: 30 to 199 beats/min.	Pressure: 0 to 294 mmHg Pulse Rate: 30 to 199 beats/min.
Pressure sensor	Electrostatic capacitive sensor	Electrostatic capacitive sensor
Applicable cuff	Wrap around cuff	Wrap around cuff
Accuracy of pressure indicator	Within ±3 mmHg or 2 % of reading	Within ±3 mmHg or 2 % of reading
Accuracy of pulse rate	Within ±5 % of reading	Within ±5 % of reading
Cuff inflation	Automatic inflation with air pump	Automatic inflation with air pump
Pressure sensor	Semiconductor pressure sensor for wrapping cuff.	Semiconductor pressure sensor for wrapping cuff.
Deflation	Automatic via electromagnetic valve	Automatic via electromagnetic valve
Exhaust	Automatic rapid exhaust via electromagnetic valve	Automatic rapid exhaust via electromagnetic valve
Power source	AC power only	AC power only

Non-Confidential Summary of Safety and Effectiveness

6-Oct-08

Model Name:	**New device HEM-9000AI-X**	**Predicate – K050233 HEM-9000AI**
Specification		
Display	Liquid crystal digital display	Liquid crystal digital display
Operating conditions	10 to 40 °C (50 to 104 °F) 15 to 85%RH	10 to 40 °C (50 to 104 °F) 15 to 85%RH
Storage conditions	-20 to 60 °C (-4 to 140 °F) 10 to 95 %RH	-20 to 60°C (-4 to 140 °F) 10 to 95 %RH
Dimensions (mm) Main unit AI Pulse Wave sensor unit AI Pulse Wave measurement unit	240 (W) × 235 (D) × 260 (H) mm 140 (W) × 60 (D) × 55 (H) mm 170 (W) × 315 (D) × 145 (H) mm	240 (W) × 235 (D) × 260 (H) mm 140 (W) × 60 (D) × 55 (H) mm 170 (W) × 315 (D) × 145 (H) mm
Weight (not including batteries) Main unit AI Measurement unit	Approx. 5.3 kg Approx. 1.3 kg	Approx. 5.3 kg Approx. 1.3 kg

The difference between the proposed HEM-9000AI-X and the HEM-9000AI is only the addition of the calculated parameter, cSBP. All other features, functions, and technologies are identical to the predicate.

Table 2 presents the similarities and differences of the proposed HEM-9000AI-X and the predicate AtCor Medical SphygmoCor Px, K012487.

Table 2 – Table of Comparison of cSBP measurement a Predicate vs. Proposed Model

Model Name:	**New device HEM-9000AI-X**	**Predicate – K012487 SphygmoCor Px**
Specification		
cSBP Measurement method	Applanation tonometry	Applanation tonometry Note that the predicate K070795 also measures cSBP

Differences Between Other Legally Marketed Predicate Devices

The HEM-9000AI-X is viewed as substantially equivalent to the following predicate devices – Omron HEM-9000AI – K050233 and AtCor Medical SphygmoCor Px – K012487 and SphygmoCor CvMs – K070795.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2008

Omron Healthcare, Inc.
c/o Promedic, Inc.
Mr. Paul E. Dryden
President, Regulatory Consultant for Omron Healthcare
24301 Woodsage Drive
Bonita Springs, FL 34134-2958

Re: K081654
Trade/Device Name: HEM 9000AI-X
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: September 6, 2008
Received: September 9, 2008

Dear Mr. Dryden:

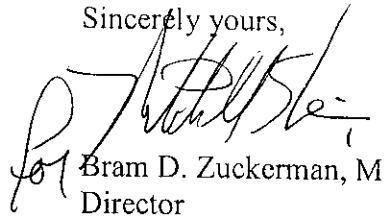
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part

807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K081654 (To be assigned)

Device Name: HEM 9000AI-X

Indications for Use:

The HEM-9000AI-X is intended to measure systolic and diastolic blood pressure and pulse rate in adults with an arm circumference of 17 - 50 cm (7-20 inches), and to calculate a radial augmentation index (AI) and central (aortic) blood pressure which is used on adult patients only.

The HEM-9000AI-X is intended for use in physicians' offices, hospitals, clinics and other medical facilities where non-invasive blood pressure and radial AI measurements/calculations are performed on patients and invasive measurement is contraindicated.

The Augmentation Index (AI) function of the HEM-9000AI-X has not been evaluated on patients who have intra-ventricular conduction delays (VCD).

Prescription Use XX or **Over-the-counter use __**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 10/10/08
Division of Cardiovascular Devices

510(k) Number K081654